

**Remarks**

The Office Action mailed March 29, 2011 has been received and reviewed. The pending claims are claims 17-26 and 29-32. Support for the amendments to the claims can be found in the specification, including the originally filed claims and examples. Reconsideration and withdrawal of the rejections are respectfully requested.

**Interview Summary**

Applicants thank Examiners Maewall and Gollamudi for the courtesy extended in the telephonic interview on June 17, 2011. During the interview, the amendments presented herein were discussed.

**The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 17-26, 28-30, and 33-34 under 35 U.S.C. §103(a) as being unpatentable over Pflug et al. (WO 98/48766) in view of Geistlich et al. (U.S. Patent No. 4,096,241). Claim 17 having been amended, this rejection is rendered moot. Insofar as the present rejection applies to the amended claims, it is respectfully traversed.

The present invention is described, for example, in paragraphs [0010], [0014], and [0015] of the published application. Taurolidine is acting as a "Trojanic Horse." It remains inactive in the dental material and develops its bactericidal activity only upon contact with microorganisms being present in the mouth of a patient. The enzymes of the active microorganisms start hydrolysing the substance taurolidine and thereby generating formaldehyde, which is toxic to the microorganisms. The mechanism of action of taurolidine is in contrast to substances such as chlorhexidine, which remain stable in the oral environment.

It is submitted that combining Pflug et al. and Geistlich et al. is not obvious. Geistlich et al. disclose oral care compositions, but not those with curable or hardenable compositions (e.g., "polymerizable component" in claim 17). Because these are such different oral care compositions, one of skill in the art would not have had a reasonable expectation of success. For example, one of skill in the art would not have expected that the curable compositions of Pflug et al. would still be curable and that the curing mechanism would not be negatively affected by the

addition of Geistlich et al.'s taurolidine. Moreover, one of skill in the art would not have expected that taurolidine would still be effective when added to the curable compositions of Pflug et al.

It may not be necessarily concluded that if one takes a substance (e.g., taurolidine) that has been used in non-curable compositions (e.g., mouthwashes, dentrifices, etc.), then that substance can also be used in curable compositions. When a substance is put into a curable composition, the substance will typically remain within the composition, especially if the composition is cured. Thus, it would be expected that the efficacy of the substance would be dramatically reduced (e.g., as compared to the substance in a liquid composition, such as mouthwash).

Surprisingly, Applicants found that a substance (e.g., taurolidine) whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms may be incorporated into a curable composition. Moreover, the structure of Geistlich et al.'s taurolidine is very much different from that of Pflug et al.'s triclosan and, thus, it may be assumed that the mechanism used by triclosan to kill germs may be different from that used by taurolidine.

Further, Pflug et al. describe triclosan as being "soluble in many organic solvents [and] stable to hydrolysis" (page 4, lines 3-5). In contrast, Geistlich et al. describe taurolidine as a formaldehyde carrier (column 1, lines 28-29) and, thus, is not stable to hydrolysis.

Pflug et al. disclose that low water solubility is advantageous: "As the water solubility of triclosan is low and it is embedded in a crosslinked polymer matrix, leaching of the triclosan is low, resulting in a long-term antimicrobial effect." (Page 6, lines 1-4, emphasis added; *see also* page 7, lines 16-21.) Thus, Pflug et al. effectively teach away from the use of taurolidine, which is water soluble. Further, in contrast, Geistlich et al. disclose use of taurolidine in toothpastes, tooth gels, and mouth washes (column 2, lines 28-32), not in a polymerizable component, particularly where the polymerizable component is used in a dental filling material, a glass ionomer cement, a temporary dental filling material, or a dental impression material.

Applicants submit that one of skill in the art would not be motivated to use taurolidine, which is not stable to hydrolysis and is water soluble, in the dental material of Pflug et al., to replace triclosan, which is stable to hydrolysis and has low water solubility.

Furthermore, there is no teaching or suggestion in either document of using taurolidine having a particle size of less than 42  $\mu\text{m}$ . Using taurolidine with a particle size of less than 42  $\mu\text{m}$  allows for a homogeneous dispersion of the substance in the polymerizable material. This homogenous dispersion facilitates a homogeneous release of the active agent.

Again, it is submitted that the Examiner, in simply stating that it would have been obvious to exchange Pflug et al.'s triclosan with Geistlich et al.'s taurolidine, has not provided adequate and proper reasoning sufficient to establish a *prima facie* case of obviousness. Once the solution to a problem is known, one can be tempted to import hindsight and allege it is obvious. Thus, Applicants respectfully submit that the Examiner's combination of Pflug et al. in view of Geistlich et al. must have been as a result of improper hindsight analysis.

The U.S. Supreme Court cautioned against such analysis in *KSR*, stating, "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (167 L.Ed.2d at 725, citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (383 U.S. at 36, quoting *Monroe Auto Equipment Co. v. Heckthorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (6<sup>th</sup> Cir. 1964))).

For at least the reasons provided herein, the Examiner has failed to establish a *prima facie* case of obviousness. Applicants respectfully request reconsideration and withdrawal of the obviousness rejection based on Pflug et al. in view of Geistlich et al.

### **Request for Rejoinder**

Withdrawn claims 31 and 32 recite subject matter that is similar to that of, for example, independent claim 17. Upon an indication of claim 17 being allowable, Applicants respectfully request that claims 31 and 32 be rejoined and examined pursuant to M.P.E.P. §821.04, which states that "[t]he propriety of a restriction requirement should be reconsidered when all the claims directed to the elected invention are in condition for allowance, and the nonelected invention(s) should be considered for rejoinder."

**Amendment and Response**

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Serial No.: 10/539,952

Confirmation No.: 8655

Filed: March 6, 2006

For: DENTAL MATERIAL CONTAINING BACTERIOSTATIC AND/OR BACTERICIDAL SUBSTANCES

**Summary**

It is respectfully submitted that the pending claims 17-26 and 29-32 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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June 28, 2011

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **Amendment**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28<sup>th</sup> day of June, 2011.

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